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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/765,695	07/25/97	ABRAHMSEN L	A96335US

HM22/0816

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EXAMINER	
SCHWADRON, R	
ART UNIT	**PAPER NUMBER**
1644	17

DATE MAILED: 08/16/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/765,695	Abrahmsen et al.
Examiner	**Group Art Unit**
Ron Schwadron, Ph.D.	1644

☐ Responsive to communication(s) filed on _____ .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *14-51* is/are pending in the application.

Of the above, claim(s) *14-35* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *36-51* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Applicant's election with traverse of Group II, claims 36-51 in Paper No. 15 is acknowledged. The traversal is on the ground(s) that are stated in said paper. This is not found persuasive because of the following reasons. The MPEP section 1850 (July 1998, 1800-51) states:

Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of another claim and is in the same category of claim as that other claim (the expression "category of claim" referring to the classification of claims according to the subject matter of the invention claimed for example, product, process, use or apparatus or means, etc.).

If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention. Equally, no problem arises in the case of a genus/species situation where the genus claim avoids the prior art. Moreover, no problem arises in the case of a combination/subcombination situation where the subcombination claim avoids the prior art and the combination claim includes all the features of the subcombination.

If, however, an independent claim does not avoid the prior art, then the question whether there is still an inventive link between all the claims dependent on that claim needs to be carefully considered. If there is no link remaining, an objection of lack of unity (that is, arising only after assessment of the prior art) may be raised. Similar considerations apply in the case of a genus/species or combination/subcombination situation.

In the instant application, the independent claim does not avoid the prior art. The putative special technical feature linking groups I and II appears to be the conjugate of group I. However, Buelow et al. teach a protein A-SEB conjugate wherein the SEB portion of the conjugate only contains amino acids 1-130 of SEB (see Figure 4), which is a conjugate encompassed by claim 1. This conjugate can bind the VB of a TCR (because it stimulates T cells, see Figure 4). It is an inherent property of said mutated conjugate that it has a modified ability to bind MHC class II antigens because it lacks SEB

residues important in MHC class II binding (eg. such as residue 227, see specification, pages 22-23). Therefore, the technical feature linking the inventions of Groups I and II does not constitute a special technical feature a defined by PCT rule 13.2, as it does not define a contribution over the prior art. Furthermore, it would have been obvious that the fusion protein taught by Buelow et al. could have been prepared using any art molecule used for preparing fusion proteins(eg. antibody or antibody fragments). The requirement is still deemed proper and is therefore made FINAL.

2. Claims 14-35 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions, the requirement having been traversed in Paper No. 15.

3. Claims 36-51 are under consideration.

4. Formal drawings have been submitted which fail to comply with 37 CFR 1.84. Please see the form PTO-948 enclosed with paper no. 8.

5. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

6. The specification, page 26, line 30 should be amended to read "Brief description of the drawings". See 37 CFR 1.77.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 36-51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the recitation of "staphylococcal enterotoxin" in claims 41,43,50. The specification, while disclosing the use of specific staphylococcal enterotoxins in the claimed invention as per claim 7, does not disclose the scope of the claimed invention. There is no support in the specification as originally filed for the conjugates recited in claims 39,40,48,49. While the specification discloses specific examples of a superantigen which requires zinc ions to bind MHC class II and specific examples of the mutant recited in claims 40 and 49, it does not disclose the scope of the claimed invention which encompasses any superantigen or mutated superantigen with aforementioned characteristics. There is no written description of the scope of the claimed inventions in the specification as originally filed (eg. the claimed inventions constitute new matter).

9. Claims 42 and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 42 and 51 are indefinite in the recitation of "the conjugate" because said claims depend on claims 36 and 50 respectively, wherein claims 36 and 50 are drawn to a method, not a conjugate.

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 36-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dohlsten et

al. (1991).

Dohlsten et al. teach SEA/ antibody conjugates wherein the SEA portion of the conjugate portion binds T cells and the antibody portion of the conjugate binds a tumor antigen (see Abstract). Dohlsten et al. teach that said conjugate can activate T cells to lyse tumor cells that express the antigen bound by the antibody portion of the SEA/antibody conjugate (see abstract). Dohlsten et al. teach that SEA binds VB of the TCR of T cells. Dohlsten et al. teach that said conjugates can be used to treat disease (see Abstract, last sentence) including cancer (see page 9291, second column). SEA is a superantigen requiring zinc ions for binding to MHC class II (eg. see claim 50). The SEA and antibody are "fused together". SEA is as staphylococcal enterotoxin (see Abstract). An antibody is a "polypeptide structure" and a "biospecific affinity counterpart" (see claim 45). Dohlsten et al. do not teach that the superantigen portion of the conjugate has been mutated to show a modified ability to bind to MHC class II. Regarding the SEA/antibody disclosed in said publication, Dohlsten et al. teach that "it would be of importance to further perturb MHC class II-dependent CTL activity by reducing the binding of the C215-SEA conjugate for MHC class II molecules" (see page 9291, column 1). Dohlsten et al. teach that MHC class II binding in SEA and other superantigens has been localized to the C-terminal region (see page 9291, first column). Dohlsten et al. teach that using such information, SEA/antibody conjugates with reduced MHC class II binding could be prepared (see column 1, page 9291). A routineer would have prepared such conjugates using routine experimentation. Dohlsten et al. teach that it would have been desirable to produce such mutated conjugates to decrease binding of the conjugate to nontumor cells which express MHC class II (see column 1, page 9291). The zinc binding region of the superantigen is found in the C-terminus. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Dohlsten et al. teach SEA/ antibody conjugates wherein the SEA portion of the conjugate portion binds T cells and the antibody portion of the conjugate binds a tumor antigen and the use of said conjugates to kill tumor cells, and Dohlsten et al. teach that "it would be of importance to further perturb MHC class II-dependent CTL activity by reducing the binding of the C215-SEA conjugate for MHC class II molecules". One of ordinary skill in the art would have been motivated to prepare such conjugates because Dohlsten et al. teach that "it would be of importance to further perturb MHC class II-dependent CTL activity by reducing the binding of the C215-SEA conjugate for MHC class II molecules".

12. No claims is allowed.

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 305-3014.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1800~~ 1600

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644
August 16, 1999